The University of New England Institutional Biosafety Committee Policies and Procedures Manual

Approved and Adopted by the UNE Institutional Biosafety Committee

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Section 1: Introduction

1.0 Purpose

It is the responsibility of The University of New England (UNE) Institutional Biosafety Committee (IBC) to review, approve and oversee the use of recombinant DNA (rDNA), biohazardous agents, materials and toxins in all research or teaching activities conducted by UNE facilities or research personnel. Together,
(IBC Policies) and the UNE Policy
set forth the relevant regulatory and local requirements. Because laboratory work can involve exposure not only to rDNA, biohazardous agents, materials and toxins, but also to chemical and radiological hazards, the IBC Policies should be used in conjunction with any other pertinent UNE policies and procedures.

1.1 Mission Statement

Ensure that UNE safeguards human health and the environment by maintaining an adherence with the ( ) and the Through a balance of outreach and support for research personnel, the IBC will:

- Assure activities meet the ethical and legal requirements for the responsible use of rDNA, biohazardous agents, materials and toxins.
- Establish policies and make recommendations to UNE regarding such activities.
- Minimize risks to the research personnel, community and the environment by educating the UNE community regarding the regulatory requirements for the use of rDNA, biohazardous agents, materials and toxins.

1.2 Authority of the IBC

The UNE IBC is responsible for the review, approval and oversight of research involving rDNA and biohazardous materials, agents and toxins in research and teaching activities. IBC responsibilities include assessing facilities, procedures, practices and training of research personnel to assure compliance with National Institutes of Health /Office of Biotechnology Activities (NIH/OBA) and other pertinent guidelines and regulations. To successfully carry out these responsibilities, the IBC is appointed to achieve sufficient knowledge and expertise in biomedical research and biosafety. The IBC has the authority to approve, require modifications to secure approval, disapprove, suspend or terminate research activities as need to assure adherence to the appropriate regulations and guidelines.

The UNE IBC is responsible for the planning and implementation of the campus Biosafety program with a purpose to ensure the health and safety of all personnel working with rDNA and biohazardous materials, agents and toxins. The IBC responsibilities include:

- Ensuring that research conducted at the Institution is in compliance with the , , and United States Department of Agriculture (USDA) regulations;
- Drafting campus policies and procedures; and
- Reviewing individual research proposals using rDNA and biohazardous materials, agents and toxins.

To the extent that UNE receives NIH funding for research involving rDNA molecules, all activities involving rDNA must follow the . Failure to adhere to these guidelines can result in suspension or termination of NIH funding, or to a requirement for prior NIH approval of any or all rDNA projects at the institution. The IBC is therefore responsible for establishing and implementing policies that provide for the safe conduct of research involving rDNA and biohazardous materials, agents and toxins to ensure adherence with , regardless of funding status or source. IBC responsibilities with regards to activities involving rDNA and biohazardous materials, agents and toxins are specified in the . The IBC has the authority to oversee all research and teaching activities involving rDNA and biohazardous materials, agents and toxins including suspension or termination of research that does not comply with IBC Policies.

1.3 Committee Composition

The President of UNE delegates the Institutional Official (IO) authority to appoint the chair, IBC members and alternates as needed. All members are voting members, and consist of faculty, research personnel, and the community. At least one member each of the UNE Institutional Review Board (IRB) and the UNE Institutional Animal Care and Use Committee (IACUC) shall be members of the UNE IBC.

The Chair shall be either:

- a scientific researcher with experience in rDNA and biohazardous materials, agents and toxins; or
- the Director of Environmental Health & Safety, if the latter has appropriate experience monitoring and evaluating research and teaching activities involving rDNA or biohazardous materials, agents and toxins

The UNE Director of Environmental Health and the UNE Director of Research Integrity shall be voting members . All other IBC membership terms are staggered for one or two years and are renewable upon mutual agreement. Members will be evaluated annually by the IO and Director of Research Integrity, on the basis of satisfactory attendance, their preparation for each meeting by reviewing the submitted research, and if they have effectively contributed to the functions of the IBC.

Additionally, the Director of Research Integrity will notify OBA of any changes in IBC membership when they occur. Such notice shall include a revised list of members, contact information and a biosketch for each new member. These annual reports and periodic updates serve three primary purposes:

To assure OBA that local review of Biosafety risks takes place;
To indicate the UNE point of contact for Biosafety matters; and
To provide a census of the field by informing OBA where rDNA research is being conducted.

1.6 Regulations and Guidelines

The IBC Policies are based upon the following regulations and guidelines:

This document specifies practices and provides guidelines for constructing and handling rDNA molecules and organisms containing rDNA molecules. Institutions conducting or sponsoring rDNA research covered by are responsible, through established policies and its IBC, for ensuring that such research is conducted in compliance with the are available online at http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm.

BMBL is published by Centers for Disease Control and Prevention (CDC) and the NIH. This document contains guidelines for microbiological practices, safety equipment, and facilities that constitute the four established biosafety levels. The BMBL is considered

2.0 Institutional Official (IO) and the University Responsibilities

The responsibility for Biosafety Program at UNE

Ensuring all research personnel, including students, have the required training in the accepted procedures for laboratory practices and safety;
Maintaining IBC approval for use of rDNA and biohazardous materials, agents and toxins through timely submission of annual updates;
Immediately reporting any significant problems or any research-related accidents and/or illnesses to EHS and any other UNE committees (IRB or IACUC) that have reviewed and approved the research activity; and
Complying with permit and shipping requirements for biohazardous materials;

2.5 Office of Biotechnology Activities (OBA) Responsibilities

OBA serves as the focal point for information on recombinant DNA activities and provides advice to all within and outside NIH.

- Monitoring Federal and state regulations, draft revised policies and procedures to remain in compliance with those regulations, and
- Providing administrative support for the IBC by scheduling meetings, arranging for meeting space and taking meeting minutes.

Section 3: Protocol/Modification Submission and Review

3.0 Submissions

The UNE IBC is responsible for overseeing and evaluating all aspects of research and teaching activities involving rDNA and biohazardous materials, agents and toxins. To this end, the UNE IBC will review proposals that involve rDNA and biohazardous materials, agents and toxins to ensure that the criteria established in the IBC Policy and the federal regulations and guidelines are implemented. In its review, the IBC's primary goal is to facilitate research personnel compliance with applicable laws, regulations, guidelines and policies consistent with the performance of appropriate and productive scientific endeavors.

The Principal Investigator is responsible for submitting IBC protocols (new, renewal or amendment) submissions to the Director of Research Integrity for IBC review and approval. No research involving rDNA and biohazardous materials, agents and toxins can be initiated until the Principal Investigator has received the approval of the IBC.

Although federal regulations allow exemptions for some types of rDNA used, the Principal

Acknowledgement Statement

I, [insert name of person with assigned research space] am aware of the attached research of [insert name of PI without assigned space] that will be conducted in space assigned to me. I acknowledge my responsibility for ensuring that this research will be conducted in a safe manner and in accordance with institutional and federal regulations.

3.1 Experiments Requiring IBC Review

Experiments that require IBC review include, but are not limited to

- Recombinant studies that are not exempt from the ;
- The deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally[4];
- The deliberate transfer of rDNA,

3.2 New Submissions

The online applications for both Biosafety a

3.4 Failure to Submit Renewal/Respond to IBC Requirements

If the Principal Investigator fails to provide a renewal form to the IBC by the anniversary date, the IBC Chair or the Director of Research Integrity will send an administrative suspension letter to the Principal Investigator, copied to the Chair/Dean of the department. All research activities pertaining to the research described in the expired protocol must cease. If the Principal Investigator does not provide a completed application for renewal by the next regularly scheduled IBC meeting, the protocol is subject to termination. Termination of the IBC protocol may require termination of any related IACUC or IRB protocols, notice to the appropriate Chair/Dean, the Institutional Official and the Office of Sponsored Programs.

3.5 Modification Process

Changes or modifications to approved protocols (e.g. changing/adding research personnel, room changes, new procedures or agents) must be reviewed and approved by the IBC prior to initiation. If the changes are extensive, or change the scope of the review, a new submission should be made.

3.6 Protocol Termination

The Principal Investigator will provide written notice to the IBC, through the Director of Research Integrity, when a research involving rDNA and biohazardous materials, agents and toxins is completed or no longer active. The IBC shall contact the Principal Investigator if there are any questions or concerns regarding Termination of Approval.

As stated in Section 3.4 above, failure to renew a previously approved IBC protocol may result in protocol termination. Additionally, non-compliance with institutional and federal regulations, policies and guidelines or requirements of the IBC that are either serious or ongoing will be evaluated and the IBC may determine that the incidents require protocol termination.

3.7 Relationships to IACUC and IRB

Occasionally, IBC protocols may involve human or animal subjects. In such cases, IBC review and approval can be made prior to, and as a condition of, approval by the UNE IRB or UNE IACUC.

Section 4: IBC Meeting Process

4.0 Requirements for Quorum

The conduct of official IBC business occurs at convened meetings that must include a quorum of members in order for the meeting to be held. The IBC defines a "quorum" as half the regular voting members, plus one. A protocol is approved only if a quorum is present, and if more tha

50% of the quorum votes in favor or protocol approval. For reasons other than conflict of interest, abstentions from voting do not alter the quorum or change the number of votes required. Members are expected to attend the convened meetings unless they have notified the IBC Chair and the Director of Research Integrity in advance of their absence. Members who fail to attend half the scheduled meetings in any given calendar year may be removed from the committee.

4.1 Protocol Review

IBC members will be provided with electronic copies of all IBC protocol applications prior to the convened meeting at which the protocol will be considered. The IBC Chair or Director of Research Integrity, if asked, will relate any pre-meeting questions or comments from committee members to the Principal Investigator. This allows for the Principal Investigator to respond to any queries or questions prior to the convened meeting.

4.2 Procedures

IBC meetings are routinely held quarterly, on dates that will be announced at the start of each academic year. Special meetings can be called if the protocol volume requires, or if matters arise that require immediate resolution. The Director of Research Integrity is responsible for assuring that a meeting room is located and scheduled and that all other arrangements for the meeting are made.

At the scheduled time and upon reaching a quorum, the IBC Chair will call the meeting to order and follow an agenda prepared prior to the meeting. The typical order of the agenda is as follows:

- Call to order and Chair's reminder to members of conflict of interest requirements.
- Approval of the previous meeting's minutes.
- IBC related announcements.
- Protocol Review.
- Educational items for discussion.
- Next meeting announcement.
- Meeting adjournment.

The UNE IBC must complete the following when reviewing protocols for initial review or periodic review of ongoing research activities:

- Determine the containment levels required by the ;
- Assess the facilities, procedures, practices, training and expertise of personnel involved in research with rDNA and/or biohazardous materials, agents or toxins; and
- Ensure compliance with the and the BMBL.

4.4 Conflict of Interest

Both the [redacted] and the IBC Policies state that no IBC member who has a direct or indirect conflict of interest in a project may participate in the IBC review or approval of that project. Examples of direct conflict of interest include, but are not limited to:

- Serving as the Principal Investigator for the project;
- Serving as faculty mentor to a student proposing the project; and/or
- Having a direct financial interest in the project.

Examples of indirect conflict of interest include, but are not limited to:

- Being related to the Principal Investigator;
- Serving as an advisor or consultant to the investigator(s); and/or
- Having an indirect financial interest in the project.

Served on the Committee and observed the procedures being proposed;
Served as reviewers for protocols involving similar procedures (where their questions were answered);
Participated in past IBC discussions about the procedures.

4.8 Meeting Frequency

Convened meetings of the IBC occur quarterly. The annual meeting schedule will be set by the Director of Research Integrity, in consultation with the IBC Chair. The Chair may call an emergency meeting of the IBC as necessary to address such issues as noncompliance or serious and/or unexpected events involving rDNA and biohazardous materials, agents and toxins, or protocols requiring "just in time" consideration.

4.9 Attendance of Non-Members

Portions of the UNE IBC meetings are considered open and, as such, members of the UNE community and the public at large may attend an IBC meeting. The IBC will conduct most non-protocol business and protocol discussion in an open session. Discussion directly relating to biosecurity measures and actual protocol deliberation will be held in executive session. When the IBC goes into executive session, the meeting becomes closed to the public, and non-member guests will be asked to leave until the work of the executive session is complete.

Section 5: Reporting Requirements

5.0 Reportable Incidents and Violations

Incidents/problems involving rDNA and biohazardous materials, agents and toxins must be immediately reported to the Biological Safety Officer (BSO) and the Director of Research Integrity.

5.1 The Principal Investigator Reporting

Certain events trigger Principal Investigator reporting duties. Reports may need to be filed internally or externally.

5.1.1 Principal Investigator Internal Reporting

The Principal Investigator and their personnel must report any significant incident, violation of the , or any significant research or teaching related accidents and illnesses immediately by contacting the BSO and the Director of Research Integrity. Examples of incidents and violations include, but are not limited to:

- Any overt human exposure, such as a needle stick, injection, splash, spill, aerosol exposure or contamination due to equipment failure;
- Any potential exposures with a high risk of contamination, such as spills, containment failure while working with the agent or equipment failure that may produce aerosols.
- A containment breach, which may be subsequently determined to pose either an overt or potential exposure individuals;

The occurrence of any illness that may be caused by the agents used in the laboratory

5.5 Response to External Requests for Information

In accordance with the NIH Guidelines, upon request, the institution will make available to the public all IBC meeting minutes and any documents submitted to or received from funding agencies which the latter are required to make available to the public. Redaction of proprietary and private information is allowed but "must be done so judiciously and consistently for all requested documents."

Section 6: Non-Compliance

6.0 Allegations

Any allegations of non-compliance or unsafe working conditions may be made to the IBC Chair, to any member of the IBC, the Director of Research Integrity (ORS) to the IO, or to the UNE Compliance Hotline[6] at 1 866 587 6636. In all instances, allegations shall be immediately forwarded to the IBC Chair and the IO. The IBC Chair and the IO are responsible for investigation and resolution of all allegations of non-compliance. The allegations and resulting investigations will remain confidential to the extent possible.

6.1 Investigation and Review Process

The IO and the IBC Chair will appoint a subcommittee to investigate the allegation. The subcommittee will inform all persons involved in the investigation of the purpose and the manner in which it will be conducted. The subcommittee, in its investigation, will examine all documents and procedures relating to the allegation and will interview individuals who are named in the allegation and others who may have knowledge of the circumstances surrounding the allegation and determine if there is a basis in fact to support the allegation. The subcommittee will report its findings to the full IBC for final determinations and recommendations (see Section 6.2).

6.2 IBC Determination

At a convened meeting, the IBC will discuss the subcommittee report and determine whether there is a consensus that the allegation of non-compliance is substantiated and, if so, determine the seriousness of the incident. All persons involved in the allegation of non compliance will be given the opportunity to appear to respond to the allegation and/or findings. Deliberations and voting on the report and recommendations will take place in a closed executive session. The IBC will inform all parties involved, including the complainant, if known, of the committee's findings.

[6] For more information about the UNE Compliance Hotline, see http://www.une.edu/compliance/hotline.cfm

NIH Guidelines training is mandatory only for Principal Investigators and research personnel performing rDNA research that is non-exempt. It is the Principal Investigator's responsibility to complete and ensure all research personnel has received the required training prior to protocol review by IBC. Documentation of successful completion of training is required in order to receive IBC approval. The IBC training courses can found at www.citiprogram.org.

Section 8: Occupational Health Services Program - Laboratory Animals and Biomedical Services (OHPLABS)

8.0 Overview

UNE provides occupational health and safety services to ensure appropriate occupational health and safety surveillance (and if necessary care) for lab personnel involved in research approved by the IBC. These services are provided through Concentra, and provided free of charge to research personnel and all information collected will maintained in a confidential manner, as required by law. Alternatively, lab personnel are free to consult with their own physicians.

8.1 Enrollment Requirement

All personnel who may be potentially exposed to biohazardous materials are strongly encouraged, and in some instances may be required, to make use of the services offered through Concentra.

8.2 Services Provided

Concentra services include:

- Medical Evaluation
- Vaccinations
- Serum Banking
- Respirator Fit Testing
- Case Management
- Consultation for medical issues